IV. Remarks

A. Amendments to the Abstract

The Abstract has been amended.

It is respectfully submitted that no new matter has been added by virtue of this amendment.

B. Status of the Claims

Claims 62, 63, 65, 69, 78, 83, and 84 have been amended without prejudice. In claims 62 and 63, a comma has been inserted before the phrase "and the second layer comprising a hydrophobic material." In claims 65 and 69, informality has been corrected ("form" was replaced with "from"). Claim 78 has been amended to recite that "... the amount of naltrexone, nalmefene, or pharmaceutically acceptable salts thereof released from the solid oral dosage form which has been tampered with and administered orally, intranasally, parenterally or sublingually will substantially block an effect of the opioid agonist ~~naltrexone, nalmefene, or pharmaceutically acceptable salts thereof~~." Support for this amendment can be found, e.g., on pages 64-66 of the specification. The preamble of claims 83 and 84 have been amended to recite "The opioid antagonist composition of any one of claims ...." Claim 84 has been further amended to use "bioequivalent to 0.125 mg naltrexone or less" language of original claim 16. Applicants submit that no new matter has been added by virtue of the present amendments.

Claims 62-85 are pending, with claim 68 withdrawn as not reading on the elected species.

Claims 62-67 and 69-85 are encompassed by the elected invention and elected species.

C. Substance of Interview

In accordance with the provisions of 37 CFR 1.133, Applicants herein make of record the substance of the telephone interview conducted on January 2, 2009, between the undersigned attorney and Examiner James Henry Alstrum-Acevedo.

During the interview, provisional double-patenting rejections (i.e., double patenting rejections made in the Office Action mailed on June 12, 2008) were discussed. A Restriction Requirement issued in connection with the parent application (U.S. Application Serial No. 09/781,081) on March 19, 2002, was also discussed.

Additionally, the Examiner was informed of (i) the Office Action issued on November 26, 2008, in U.S. Serial No. 10/700,861, and (ii) the Office Action issued on November 25, 2008, in U.S. Serial No. 10/689,866, both applications having identical specification and priority claims as the present application.

Applicants respectfully request that the substance of interview be made of record.

D. Claim Objections

Claims 65 and 69 were objected to for containing an informality (the word "from" was misspelled as "form" on line 3 of claim 65 and line 4 of claim 69).

Claims 65 and 69 have been amended without prejudice to correct the informality.

Withdrawal of the objection is respectfully requested.

E. Specification

The Examiner stated that "Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification."

In response, Applicants submit that the specification has been checked for typographical errors.

F. Claim Rejections- 35 U.S.C. § 112

Claim 84 was rejected under 35 U.S.C. § 112, first paragraph, allegedly as failing to comply with the written description requirement (new matter).

The rejection is respectfully traversed.

However, to expedite allowance, claim 84 has been amended without prejudice to use "bioequivalent to 0.125 mg naltrexone or less" language of original claim 16.

Withdrawal of the rejection is respectfully requested.

G. Double Patenting Rejections

1. U.S. Patent No. 6,696,088

Claims 65-67, 69-72, 77-78, and 81-85 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-33 and 39-40 of U.S. Patent No. 6,696,088.

The rejection is respectfully traversed.

U.S. Patent No. 6,696,088 issued from U.S. Application Serial No. 09/781,081 ("the '081 application"), which is the "parent" of the present application. On March 19, 2002, the Patent Office issued a Restriction Requirement in the '081 application. A copy of the Restriction Requirement is attached as Appendix A. A copy of the claims subject to restriction is attached as Appendix B.

In the Restriction Requirement, the Patent Office took a position that claims pending in the '081 application at that time were directed to six distinct inventions—Groups I to VI, as defined in the Restriction Requirement. It was specifically stated that "[i]nventions Group II and Group VI are unrelated." *See Restriction Requirement, page 6.*

In response to the Restriction Requirement, Applicants elected claims of Group VI (claims 100-105) for prosecution in the '081 application, and filed the present application with claims corresponding to Group II (claims 62-64, 75-80, 90-94, drawn to bi-layer composition, classified in class 424), along with four other applications (each containing claims directed to Group I, Group III, Group IV or Group V, respectively), before the '081 application issued as a patent.

Despite the fact that the present application was filed before the grant of U.S. Patent No. 6,696,088 and in response to the Restriction Requirement in U.S. Patent No. 6,696,088, a filing of a Terminal Disclaimer over the claims of U.S. Patent No. 6,696,088 is now requested by the Office.

The Manual of Patent Examining Procedure states that, where the Office has made a requirement for restriction, "[t]he third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent." *See MPEP, section 804.01; see also MPEP, section 806 ("... [w]here restriction is required by the Office double patenting cannot be held ...").*

It is therefore respectfully submitted that a request to file a Terminal Disclaimer over the claims of U.S. Patent No. 6,696,088 contravenes the third sentence of 35 U.S.C. § 121, so that a Terminal Disclaimer should not be required under the present circumstances. *See MPEP, section 804.01.* However, to advance prosecution of the present application, a Terminal Disclaimer over the claims of U.S. Patent No. 6,696,088 is being filed herewith.

Applicants submit that filing of this terminal disclaimer shall not be construed as an admission of (i) the propriety of the rejection, or (ii) that the present claims are not patentably distinct from the claims of U.S. Patent No. 6,696,088. *See, e.g., MPEP, section 804.02(II) ("[t]he filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection").*

Withdrawal of the obviousness type double-patenting rejection is respectfully requested.

2. U.S. Application No. 10/401,111

Claims 62-63, 75-76, 79-80, and 83-85 were provisionally rejected on the ground of non-statutory obviousness-type double patenting over claim 41 of copending Application No. 10/401,111.

The present application was filed on November 4, 2003, and claims priority to U.S. Application Serial No. 09/781,081[1], filed on February 8, 2001. The specification of the present application was amended in the Response filed on January 24, 2008, to contain a specific reference to the '081 application. The present application is therefore entitled to the benefit of the filing date of the '081 application (i.e., February 8, 2001). *See, e.g., 35 U.S.C. § 120 ("[a]n application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment*

[1] The U.S. Serial No. 09/781,081 has the identical specification as the present application.

of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application").

Copending Application No. 10/401,111 was filed on March 26, 2003, and claims priority to U.S. Serial No. 60/367,832, filed on March 26, 2002. The filing dates of the '111 application and its priority application are both after the filing date of the '081 application. The present application, which is entitled to the benefit of the filing date of the '081 application (i.e., February 8, 2001), is therefore an earlier-filed application than the '111 application.

The Manual of Patent Examining Procedure states:

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier-filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer ...

See MPEP, section 804.

The Manual of Patent Examining Procedure therefore mandates that the present application be allowed to issue as a patent without a terminal disclaimer over the claims of the '111 application, which is a later-filed application. *See MPEP, section 804.*

3. U.S. Application Serial No. 10/524,334

Claims 62-64, 75-76, 79-80, and 83-85 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 2-3 and 15-17 of copending Application No. 10/524,334.

The rejection is respectfully traversed.

As stated above, the present application is entitled to the benefit of the filing date of the '081 application (i.e., February 8, 2001). *See 35 U.S.C. § 120.*

Copending Application No. 10/524,334 was filed on February 11, 2005, as a National Stage of PCT/US03/25601, filed on August 15, 2003, which claims a benefit to U.S. Serial No. 60/403,711, filed on August 15, 2002. The filing dates of the '334 application and its priority application are both after the filing date of the '081 application. The present application, which is entitled to the benefit of the filing date of the '081 application (i.e., February 8, 2001), is therefore an earlier-filed application, as compared to the '334 application.

The Manual of Patent Examining Procedure therefore mandates that the present application be allowed to issue as a patent without a terminal disclaimer over the claims of the '334 application, which is a later-filed application. *See MPEP, section 804.*

Withdrawal of the rejection is therefore respectfully requested.

4. U.S. Application No. 10/689,866

Claims 65-67, 69-74, and 77-78, and 81-85 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-7, 19, 21, 24-26, 59 and 63 of copending Application No. 10/689,866.

As stated above, the present application was filed in response to the Restriction Requirement issued on March 19, 2002, in connection with the '081 application. Group II of the Restriction Requirement encompassed the claims of the present application, and Group I of the Restriction Requirement (i.e., claims 1-59 and 61 of the '081 application) encompassed claims of the copending Application No. 10/689,866, also filed in response to the Restriction Requirement and before the '081 application issued as a patent. It was specifically stated in the Restriction Requirement that "[i]nventions of Group I and Group II are unrelated." *See Restriction Requirement, page 4.*

Therefore, it is respectfully submitted that, for the reasons set forth above with regard to the double-patenting rejection over the claims of U.S. Patent No. 6,696,088, a request to file a Terminal Disclaimer over the claims of copending Application Serial No. 10/689,866 contravenes the third sentence of 35 U.S.C. § 121, and a Terminal Disclaimer should not be required under the present circumstances. However, to advance prosecution of the present application, a Terminal Disclaimer over the claims of copending Application Serial No. 10/689,866 is being submitted herewith.

Applicants submit that filing of this terminal disclaimer shall not be construed as an admission of (i) the propriety of the rejection, or (ii) that the present claims are not patentably distinct from the claims of copending Application Serial No. 10/689,866. *See, e.g., MPEP, section 804.02(II) ("[t]he filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection").*

Withdrawal of this double patenting rejection is respectfully requested.

5. U.S. Application No. 10/700,893

Claims 65-67, 69-72, and 75-85 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 62, 64 and 70-82 of copending Application No. 10/700,893.

As stated above, the present application was filed in response to the Restriction Requirement issued on March 19, 2002, in connection with the '081 application. Group II of the Restriction Requirement encompassed the claims of the present application, and Group IV (i.e., claims 69-74 of the '081 application) of the Restriction Requirement encompassed the claims of copending Application No. 10/700,893, also filed in response to the Restriction

Requirement and before the '081 application as a patent. It was specifically stated in the Restriction Requirement that "[i]nventions of Group II and Group IV are unrelated." *See Restriction Requirement, page 5.*

Therefore, it is respectfully submitted that, for the reasons set forth above with regard to the double-patenting rejection over the claims of U.S. Patent No. 6,696,088, a request to file a Terminal Disclaimer over the claims of copending Application Serial No. 10/700,893 contravenes the third sentence of 35 U.S.C. § 121, and a Terminal Disclaimer should not be required under the present circumstances. However, to advance prosecution of the present application, a Terminal Disclaimer over the claims of copending Application Serial No. 10/700,893 is being filed herewith.

Applicants submit that filing of this terminal disclaimer shall not be construed as an admission of (i) the propriety of the rejection, or (ii) that the present claims are not patentably distinct from the claims of copending Application Serial No. 10/700,893. *See, e.g., MPEP, section 804.02(II) ("[t]he filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection").*

Withdrawal of this double patenting rejection is respectfully requested.

6. U.S. Application No. 10/700,906

Claims 62-63 and 65-67 and 75-85 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 75-78, 80 and 87-97 of copending Application No. 10/700,906.

As stated above, the present application was filed in response to the Restriction Requirement issued on March 19, 2002, in connection with the '081 application. Group II of the Restriction Requirement encompassed the claims of the present application, and Group V (i.e., claims 100-105 of the '081 application) of the Restriction Requirement encompassed the claims of copending Application No. 10/700,906, also filed in response to the Restriction Requirement and before the '081 application issued as a patent. It was specifically stated in the Restriction Requirement that "[i]nventions of Group II and Group V are unrelated." *See Restriction Requirement, page 6.*

Therefore, it is respectfully submitted that, for the reasons set forth above with regard to the double-patenting rejection over the claims of U.S. Patent No. 6,696,088, a request to file a Terminal Disclaimer over the claims of copending Application Serial No. 10/700,906 contravenes the third sentence of 35 U.S.C. § 121, and a Terminal Disclaimer should not be required under the present circumstances. However, to advance prosecution of the present applicatione, a Terminal Disclaimer over the claims of copending Application Serial No. 10/700,906 is being submitted herewith.

Applicants submit that filing of this terminal disclaimer shall not be construed as an admission of (i) the propriety of the rejection, or (ii) that the present claims are not patentably distinct from the claims of copending Application Serial No. 10/700,906. *See, e.g., MPEP, section 804.02(II) ("[t]he filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply*

serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection").

Withdrawal of this double patenting rejection is respectfully requested.

V. Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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